K052201

SOLANAS™ Posterior Stabilization System
510(k) SUMMARY
August 2005

NOV 10 2005

I. **Company**: Alphatec Spine, Inc.
2051 Palomar Airport Road
Suite 100
Carlsbad, CA 92011, USA
(760) 431-9286

II **Contact Person**: Ellen Yarnall, Vice President of Compliance, Regulatory Affairs and Quality Assurance

III **Trade/Proprietary Name**: SOLANAS™ Posterior Stabilization System

IV **Product Description**:

The SOLANAS™ Posterior Stabilization System is a spinal fixation system intended to improve stability of the cervical and upper thoracic spine, C1-T3. There are a variety of implants that can be used for this procedure including cervical hooks, polyaxial pedicle screws and rods. All components are made from titanium alloy (ASTM F136).

V. **Classification**

KWP (21 CFR 888.3050)	Pedicle Screw Spinal System
MNI (21 CFR 888.3070)	Spinal Interlaminal Fixation Orthosis

VI **Indications for Use**

Indications for Use: It is intended that this device, in any system configuration, be removed after development of solid fusion mass. Hook components are indicated for use at C1-C7. Polyaxial screws are limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. These screws are not intended for placement in the cervical spine.

1. Degenerative disk disease (DDD), defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
2. Spondylolisthesis
3. Spinal stenosis
4. Fracture/Dislocation
5. Atlanto/Axial fracture with instability
6. Revision of previous cervical spine surgery
7. Tumors

VII **Substantial Equivalence**:

The SOLANAS™ Posterior Stabilization System is substantially equivalent to Summit™ system (K002733).

VIII **Performance Data**:

Mechanical testing of the SOLANAS™ Posterior Stabilization System was performed and submitted in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 2005

Ellen A. Yarnall
Vice President, RA/QA
Alphatec Spine, Inc.
2051 Palomar Airport Road, Suite 100
Carlsbad, California 92011

Re: K052201
Trade/Device Name: SOLANAS™ Posterior Stabilization System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP, MNI
Dated: October 27, 2005
Received: October 28, 2005

Dear Ms. Yarnall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K052261

Device Name: SOLANAS™ Posterior Stabilization System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(510(k) Number K052201

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